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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,491	09/08/2003	Peter Nash	93485	2025

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EXAMINER	
HUYNH, PHUONG N	

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/658,491	NASH ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) *13-17 and 30-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12, 18-29 and 36-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-42 are pending.

2. Claims 13-17, and 30-35 are withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to non-elected inventions.

3. In view of the amendment filed 5/2/06, the following objection and rejections remain.

4. The disclosure stands objected to because of the following informality: the unit for "250μ" on page 20, last line is missing. It is not clear if it is 250μl or 250μg.

It is note that the replacement paragraph contains typographical error "2501 μl".

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 3, 5-7, 18, 36, and 40-42 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The claims encompass a method of producing egg antibody to any lactic acid producing bacteria as a microbial adherence inhibitor for administration to food animals.

The specification does not reasonably provide a **written description** of *any* lactic acid producing bacteria for the claimed methods.

The specification discloses only three bacteria *Streptococcus bovis, Lactobacillus spp* and *Fusobacterium necrophorum* whose colonization resulted in acidosis in food animal. Said bacteria are used as an immunogen for a method of producing egg antibody microbial inhibitor for administration to food animals to control the incidence of acidosis in food animal. The method comprises inoculating female birds, in or about to reach their egg laying age, with a lactic acid producing immunogen *Streptococcus bovis* or SB antigen from *Streptococcus bovis* produced by the method disclosed on page 17, allowing a period of time to permit the production

in the birds and eggs laid by the birds of antibody specific to *Streptococcus bovis*, harvesting the eggs laid by the birds, and separating the antibody-containing contents of said harvested eggs from the eggshells, drying the total egg antibody-containing contents of the harvested eggs from the eggshells alone or onto feed carrier such as dry soy or rice husks, distributing the resulting egg mixture antibody product uniformly through animal feed or water and supplying the resulting antibody-containing animal feed or water to food animal to substantially prevent the adherence of *Streptococcus bovis* to the rumen or intestinal tracts of the animals.

Other than the specific bacteria mentioned above, there is inadequate written description about any other lactic acid producing bacteria, much less for using the undisclosed bacteria for making IgY antibody as a microbial adherence inhibitor for administration to any and all food animals for the claimed methods.

Since the specification discloses only a microbial inhibitor produced by inoculating female bird with *streptococcus bovis*, *Lactobacillus spp* or *Fusobacterium necrophorum*, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.*

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

7. The filing date of the instant claims is deemed to be the filing date of the instant application 10/658,491, as the parent applications 10/038,260 filed 1/7/02, 09/616,843 filed 07/14/00 and provisional applications 60/201,268 filed 5/2/00 and 60/143,985 filed 7/15/99 do not support the claimed limitations of a method of production of a microbial adherence inhibitor for administration of food animal to control the *incidence of acidosis* in food animal by inoculating female birds with colony forming *lactic acid producing immunogen*, and said colony forming immunogen is from the class of *Streptococcus bovis* and liquid extender such as liquid molasses and PBS of the instant application.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

9. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. Claims 1, 3 and 18 stand rejected under 35 U.S.C. 102(e) as being anticipated by US Pat No 6,419,926 B2 (filed April 8, 1998; PTO 892).

The '926 patent teaches an egg antibody microbial adherence inhibitor to control the incidence of acidosis such as ulcer caused by lactic acid producing immunogen or bacteria such as *Helicobacter pylori* (see col. 6, lines 46-54, in particular). The reference microbial inhibitor is provides as a food additive (see col. 5, lines 14-15, in particular). A product is a product, irrespective of its intended use such as "for administration to food animal" as recited in claim 18. The reference egg antibody microbial adherence inhibitor is produced by inoculating female birds such as hens with bacteria such as *Helicobacter pylori* (see col. 7 through col. 9, lines 1-7, in particular), allowing a period of time such as six weeks sufficient to permit the production in the birds of antibody to the reference lactic acid producing immunogen (see col. 5, lines 55, col. 7, lines 4-9, col. 8, lines 56-67, in particular), harvesting the eggs laid by the bird (see col. 9, lines 1-3, in particular), separating the antibody-containing contents of said eggs from the shells without fractionation (see col. 6, lines 25-27, in particular). The reference method of making microbial adherence inhibitor includes drying the whole egg antibody containing contents without fractionation by conventional technique such as spray drying or lyophilizing (see col. 6, lines 25-33, in particular). The reference egg antibody microbial inhibitor can prevent the adhesion of the reference lactic acid producing bacteria from adhering to the digestive tracks of mammals (see col. 6, lines 38-45, in particular). The reference egg antibody can be used as a solution or an emulsion or as a solid such as powder or granules by drying or mixed in a pharmaceutical acceptable carrier if desired (see col. 6, lines 65-67 bridging col. 7, lines 1-25, in particular). The reference egg antibody that binds to lactic acid producing bacteria inherently also prevents the

adherence of HP in the rumen or intestinal tracts of food animals. Thus, the reference teachings anticipate the claimed invention.

Applicants' arguments filed 1/17/06 have been fully considered but are not found persuasive.

Applicants' position is that the '926 patent describes inoculation of hens with H pylori to produce antibodies that prevent the adhesion of Hp to gastric mucosa and inhibit the growth of Hp in the stomach. The mention of lactic acid bacteria in the '926 patent is the use of such bacteria along with the Hp antibodies to prevent the adhesion of Hp to gastric mucosa and to inhibit the growth of Hp in the stomach. There is no disclosure in the '926 patent of inoculating the hens with lactic acid bacteria. For example, in column 6, lines 60-64 it is stated that: the antibodies (referring to Hp antibodies) can be used in combination with at least one organism selected from lactic acid bacteria, and Enterococcuses, yeasts and Bacillus in prevention or treatment of these diseases or can be added to a food for prevention of these diseases."

Further, in Experiment 3, describes the oral administration of *Lactobacillus salivious* and its effect of reducing or eliminating Hp from the stomach. It is the bacteria that are delivered orally and not the antibody to the bacteria.

In response, the argument with respect to claims 2, 4 and 19 is moot since the rejection of said claims has been withdrawn. Claim 1 and 3 are drawn to a method of producing bird antibody to any lactic acid producing bacteria. Claim 18 is drawn to any egg antibody to any lactic acid bacteria as a microbial adherence inhibitor. The '926 patent teaches method of making egg antibody as well as using the egg antibody to lactic acid producing bacteria such as *Helicobacter pylori* as a microbial adherence inhibitor to control colonizing of said bacteria and to reduce the incidence of acidosis (see col. 6, lines 46-54, in particular).

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103(a) that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1-4, 8-9, 18-21 and 25-26, 36-37, and 40 stand rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (Jan 1992; PTO 1449) in view of US Pat No 6,287,555 B1 (filed May 13, 1998; PTO 892).

The '895 patent teaches a method of producing a microbial adherence inhibitor such as egg antibody that binds specifically to colony-forming immunogen such as *E coli* that inhibits the microbacteria from adhering to the intestinal track of livestock. The reference microbial adherence inhibitor is egg antibody, which is produced by the method of inoculating an egg laying female birds such as the hen in their egg laying age with an immunogen such as bacterium *E coli*, wherein the reference *E coli* is a colony-forming bacteria (See column 5, lines 29-30, in particular), allowing a period of time such as a few weeks after inoculation sufficient to permit the production of bird antibody that binds to the targeted immunogen such as *E Coli* (See column 5, lines 47-60, column 6, 10-18, in particular). The reference method includes harvesting the eggs laid by the hens (See column 6, line 1, in particular), separating the antibody containing contents of both the yolk and albumin from the shells (See column 6, lines 19-20, in particular), drying the separated egg antibody from the shells by spray drying or lyophilizing to form powder product (See column 6, line 24-25, in particular). The dried egg antibody is used as an additive to food for animal or in a liquid carrier such as milk to livestock to prevent adherence of the targeted immunogen in the intestinal tract of the animal (See column 9, line 42-46, column 10, line 30, column 5 lines 29 bridging column 6, lines 1-49, column 9, lines 43-57, column 10, line 29-31, in particular). The '895 patent teaches antibody containing egg powder from eggs of immunized hen against the bacterium is useful as additives in foods for treatment of various disease in livestock (see summary of invention, in particular).

The claimed invention in claim 1 differs from the teachings of the reference only in that the colony-forming bacteria is lactic acid producing bacteria.

The claimed invention in claims 2 and 4 differs from the teachings of the reference only in that the colony-forming bacteria is *Streptococcus bovis*.

The '555 patent teaches bacteria such as *Streptococcus bovis* and/or *Lactovacillus spp* is an important lactic acid bacterium in the rumen of livestock, which contributes to the development of lactic acidosis (see entire document, abstract, col. 1, lines 15-30, col. 3, lines 12-20, in particular). The '555 patent teaches the risk of lactic acidosis can be reduced by immunization against *S. bovis* to produce antibody that binds specifically to *S. bovis* (see claims of '555, in particular). The '555 patent further teaches the immunogen is SB antigen from

Streptococcus bovis by culturing the bacterium in RSY-II medium for 6 to 10 h at 38.5 C, the bacterial cells suspension was used as SB antigen for the reference method (see col. 6, lines 47-61, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to substitute the bacteria such as the *E coli* as taught by the '895 patent for the lactic acid producing colony-forming bacteria such as *Streptococcus bovis* or SB antigen from *Streptococcus bovis* or *Lactovacillus spp* as taught by the '555 patent. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because *Streptococcus bovis* and *Lactovacillus spp* are an important lactic acid bacterium in the rumen of livestock, which contributes to the development of lactic acidosis and vaccination against *Streptococcus bovis* and *Lactovacillus spp* is useful for reducing acidosis as taught by the '555 patent (see abstract, in particular). The '895 patent teaches antibody containing egg powder from eggs of immunized hen against the bacterium of interest is useful as additives in foods for treatment of various disease in livestock (see summary of invention, in particular). The step of drying of antibody containing contents alone or coating the dry feed carrier with the antibody containing contents of the eggs for uniformly distribution of the antibody prior to supplying the antibody containing content in the food or water is an obvious variation of the reference teachings since the '895 patent teaches drying the separated egg antibody from the shells by spray drying or lyophilizing to form powder product to be used as food additive for livestock (See column 6, line 24-25, in particular).

Applicants' arguments filed 1/17/06 have been fully considered but are not found persuasive.

Applicants' position is that first, there must be some suggestion or motivation, either in the references themselves or the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Applicant would like to address the second criteria without acknowledging that the first and third criteria have been met, since applicant believes that only a discussion of the second criteria is necessary to obviate the rejection under 35 U.S.C. § 103(a). In other words, the court held that one cannot conclude that a given embodiment is simultaneously

obvious under §103(a) and then not enabled under § 112, first paragraph. The Office Action states that "the motivation is there because *Streptococcus bovis* is an important lactic acid bacteria in the rumen of livestock". The Office Action does not need to cite the '555 patent for that proposition. The fact that S. bovis is an important lactic acid bacteria virus is well known since the early 1970s, if not earlier. Of course, the making of antibodies to *S. bovis* is old. However, the fact that *S. bovis* is an important lactic acid bacteria in the rumen of livestock does not in and of itself include a motivation to do what applicant has done. There must be a reason or suggestion in the art for selecting the procedure used other than the knowledge learned from applicant's disclosure. In essence the standard that the Office Action is using based on the importance of S. bovis as a lactic acid producing bacterium in the rumen of livestock is that it would be obvious to try the procedure disclosed in the '895 patent with S. bovis. An obvious to try standard is not an acceptable standard as discussed in the MPEP. This is especially true in the present situation, in which the '895 patent describes a procedure using an entirely different species of bacterium of an entirely different genus, while the '555 patent describes making an antibody using another species of bacteria in yet an entirely different genus.

In contrast to applicants' argument that there is no reasonable expectation of success, the teachings of the '895 patent pertaining to the success of making egg antibody to any colony-forming bacteria such as *E Coli* and the success of using such antibody as a microbial adherence inhibitor to inhibit said bacteria from colonizing the intestinal tract of livestock while the teachings of the '555 patent pertaining to colony forming bacteria *Streptococcus bovis* and/or *Lactobacillus spp* as an important lactic acid bacterium in the rumen of livestock would have led one of ordinary skill in the art at the time the invention was made to produce egg antibody to *Streptococcus bovis* or *Lactobacillus spp* as a microbial inhibitor to prevent *Streptococcus bovis* and/or *Lactobacillus spp* from colonizing the intestinal tract of livestock. The motivation to combine the references is that egg antibody can easily be produced inexpensively any time of the year, and egg antibody can be used as food additive as taught by the '895 patent (see summary of invention, col. 3, line 50-60, in particular). The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage discovered by applicant. See MPEP 2144.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on

obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. In re McLaughlin, 170 USPQ 209 (CCPA 1971).

In contrast to applicant's assertions of the rejection is based upon an "obvious-to-try" standard; it is by now well understood that the ultimate conclusion of law that claimed subject matter as a whole would have been obvious under 35 USC 103 may at times properly be drawn from an inference of fact arising from prior art teachings which could be considered an inference that it would be "obvious to try" that which is claimed. In re O'Farrell, 853 F.2d 894, 7 USPQ 2d 1973 (Fed. Cir. 1988); Contour Saws Inc. v. Starrett Co., 444 F. 2d 433, 170 USPQ 433 (Ct.App. 1977); In re Marzocchi, 439 F. 2d 220, 169 USPQ 367 (CCPA 1977); In re Lindell, 385 F. 2d 435, 155 USPQ 521 (CCPA 1967). The evidence of purported unobvious results of record in this application is insufficient to overcome the inference of fact in this case. Therefore the above claims remain rejected under 35 USC 103 for the reasons above and also those set forth in the previous Office action.

13. Claims 5-7, 10-12, 22-24, 27-29, 38-39, and 41-42 stand rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (Jan 1992; PTO 1449) in view of US Pat No 6,287,555 B1 (filed May 13, 1998; PTO 892) as applied to claims 1-4, 8-9, 18-21 and 25-26, 36-37, and 40 mentioned above and further in view of and US Pat No 4,748,018 (May 31, 1988; PTO 1449), US Pat No. 3,878,298 (April 15, 1975; PTO 892) and US Pat No. 4,166,867 (Sept 1979, PTO 892).

The combined teachings of the '895 patent and the '555 patent have been discussed supra.

The claimed invention in claims 5 and 10 differs from the references only in that the method includes providing a dry feed carrier material, said drying the separated antibody containing contents of said eggs is achieved by coating dry feed carrier material with the antibody-containing contents of said eggs.

The claimed invention in claims 6 and 11 differs from the references only in that the method wherein the dry feed carrier material includes soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains or beet pulp.

The claimed invention in claims 7, 12 and 41 differs from the references only in that the method includes mixing the antibody-containing contents of the eggs with a liquid extender palatable to the food animal.

The claimed invention in claims 22 and 28 differs from the references only in that the microbial adherence inhibitor includes the dry feed carrier includes soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains or beet pulp.

The claimed invention in claims 23, 27, and 29 differs from the references only in that the microbial adherence inhibitor includes a liquid extender mixed with the antibody-containing contents of the eggs.

The claimed invention in claim 24 differs from the references only in that the microbial adherence inhibitor includes a liquid extender wherein the liquid extender is liquid molasses palatable to the food animal.

The '018 patent teaches avian antibody can be administered to a mammalian subject either directly as is, or is combined with a conventional pharmaceutically acceptable liquid or solid carrier (see col. 6, lines 60-66, in particular). The dehydrated egg antibody (dried egg antibody) can be used in the form of premixed food products or can be mixed in the feeding stage (see col. 9, lines 4-8, in particular).

The '298 patent teaches molasses are useful as feed additive in liquid feed formulations and molasses are widely used in feed mixing plants or growing farms (see col. 2, lines 27-62, in particular). The '298 patent further teaches various carriers such as soy bean meal, corn, cotton seed hulls, oats, barley for ruminant animals (see col. 4, lines 22-47, in particular). The supplemental animal feeds may contain cotton seed hulls that contain cellulosic roughage (see col. 4, lines 40-47, in particular).

The '867 patent teaches a method of making a high performance palatable horse feed comprising soybean hulls, rice hulls cottonseed hulls which provide the fibrous material and cereal grain such as corn and distilled dried grains provide the carbonaceous materials along with nutritional supplement (See column 3, lines 24-26, column 3, lines 10-18, claims of '867, in particular) while beet pulp provides high energy values (See column 2, line 12-13, in particular). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular). The term "includes"

is open-ended. It expands the dry feed carrier such as soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains or beet pulp to include something else.

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to mix the dry feed carrier such as soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp as taught by the '867 patent or the '298 patent or the liquid extender (carrier) such as molasses as taught by the '298 with the appropriate egg antibody that is specific for colony-forming lactic acid producing *Streptococcus bovis* as taught by the '555 patent and the '895 patent. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because the '018 patent teaches avian antibody can be administered to a mammalian subject either directly as is, or is combined with a conventional pharmaceutically acceptable liquid or solid carrier (see col. 6, lines 60-66, in particular). The '298 patent teaches liquid carrier such as molasses are useful as feed additive in liquid feed formulations and molasses are widely used in feed mixing plants or growing farms (see col. 2, lines 27-62, in particular) and various carriers such as soy bean meal, corn, cotton seed hulls, oats, barley are widely use as a carrier for ruminant animals (see col. 4, lines 22-47, in particular). The supplemental animal feeds may contain cotton seed hulls that contain cellulosic roughage (see col. 4, lines 40-47, in particular). The '867 patent teaches the carrier material such as soybean hulls, rice hulls and cottonseed hulls provide the fibrous material and provide adequate structural strength or integrity to the final feed pellets to effect stool normality (See column 3, lines 14-16, in particular). The '878 patent teaches hyperimmunized spray-dried egg powder is useful for mixing with any animal feed or sprayed directly to coat the food pellets to maintaining antibody titers (See column 9, lines 37-46). The '555 patent teaches *Streptococcus bovis* is an important lactic acid bacterium in the rumen of livestock, which contributes to the development of lactic acidosis and the risk of lactic acidosis can be reduced by antibody that binds specifically to *S. bovis* (see abstract, in particular). The '895 patent teaches antibody containing egg powder from eggs of immunized hen against the specific bacterium which induces the disease is useful as additives in foods for treatment of various disease in livestock (see summary of invention, in particular). It is within the purview of one ordinary skill in the art to distribute the dried egg antibody product uniformly throughout animal feed or water as food additive or distributing the resulting egg mixture antibody directly without drying first by

coating the animal feed uniformly with the egg antibody containing content or water as food additive as taught by the '018 patent or '895 patent. Claims 36 and 40 are obvious variation of the references teachings.

Applicants' arguments filed 1/17/06 have been fully considered but are not found persuasive.

Based on the discussion with regard to the combination of the '895 patent with the '555 patent, it is believed that this rejection under 35 U.S.C. § 103(a) cannot also be maintained, for the reasons previously stated.

In response, Applicants' position is that first, there must be some suggestion or motivation, either in the references themselves or the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Applicant would like to address the second criteria without acknowledging that the first and third criteria have been met, since applicant believes that only a discussion of the second criteria is necessary to obviate the rejection under 35 U.S.C. § 103(a). In other words, the court held that one cannot conclude that a given embodiment is simultaneously obvious under §103(a) and then not enabled under § 112, first paragraph. The Office Action states that "the motivation is there because *Streptococcus bovis* is an important lactic acid bacteria in the rumen of livestock". The Office Action does not need to cite the '555 patent for that proposition. The fact that S. bovis is an important lactic acid bacteria virus is well known since the early 1970s, if not earlier. Of course, the making of antibodies to *S. bovis* is old. However, the fact that *S. bovis* is an important lactic acid bacteria in the rumen of livestock does not in and of itself include a motivation to do what applicant has done. There must be a reason or suggestion in the art for selecting the procedure used other than the knowledge learned from applicant's disclosure. In essence the standard that the Office Action is using based on the importance of S. bovis as a lactic acid producing bacterium in the rumen of livestock is that it would be obvious to try the procedure disclosed in the '895 patent with S. bovis. An obvious to try standard is not an acceptable standard as discussed in the MPEP. This is especially true in the present situation, in which the '895 patent describes a procedure using an entirely different species of bacterium of an entirely different genus, while the '555 patent describes making an antibody using another species of bacteria in yet an entirely different genus.

In contrast to applicants' argument that there is no reasonable expectation of success, the teachings of the '895 patent pertaining to the success of making egg antibody to any colony-forming bacteria such as *E Coli* and the success of using such antibody as a microbial adherence inhibitor to inhibit said bacteria from colonizing the intestinal tract of livestock while the teachings of the '555 patent pertaining to colony forming bacteria *Streptococcus bovis* and/or *Lactobacillus spp* as an important lactic acid bacterium in the rumen of livestock would have led one of ordinary skill in the art at the time the invention was made to produce egg antibody to *Streptococcus bovis* or *Lactobacillus spp* as a microbial inhibitor to prevent *Streptococcus bovis* and/or *Lactobacillus spp* from colonizing the intestinal tract of livestock. The motivation to combine the references is that egg antibody can easily be produced inexpensively any time of the year, and egg antibody can be used as food additive as taught by the '895 patent (see summary of invention, col. 3, line 50-60, in particular). The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage discovered by applicant. See MPEP 2144.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. In re McLaughlin, 170 USPQ 209 (CCPA 1971).

In contrast to applicant's assertions of the rejection is based upon an "obvious-to-try" standard; it is by now well understood that the ultimate conclusion of law that claimed subject matter as a whole would have been obvious under 35 USC 103 may at times properly be drawn from an inference of fact arising from prior art teachings which could be considered an inference that it would be "obvious to try" that which is claimed. In re O'Farrell, 853 F.2d 894, 7 USPQ 2d 1973 (Fed. Cir. 1988); Contour Saws Inc. v. Starrett Co., 444 F. 2d 433, 170 USPQ 433 (Ct.App. 1977); In re Marzocchi, 439 F. 2d 220, 169 USPQ 367 (CCPA 1977); In re Lindell, 385 F. 2d 435, 155 USPQ 521 (CCPA 1967). The evidence of purported unobvious results of record in this application is insufficient to overcome the inference of fact in this case. Therefore the above

claims remain rejected under 35 USC 103 for the reasons above and also those set forth in the previous Office action.

14. The following new ground of rejection is necessitated by the amendment filed 5/2/06.

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

16. Claims 1 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The "bacteria" in claim 1, line 6 is inconsistent with the "bacterium" in claim 1, line 9. One of ordinary skill in the art cannot appraise the metes and bound of the claimed invention.

The "bacteria" in amended claim 40 is inconsistent with the "immunogen" in claim 40, lines 3 and 4.

17. No claim is allowed.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The

examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.

20. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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July 21, 2006

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